

Application Number 10/825,955  
Amendment in response to Final Office Action mailed May 6, 2008

### **REMARKS**

This Amendment is responsive to the Final Office Action dated May 6, 2008. Applicant has amended claims 1, 4-6 and 10-13; canceled claims 69-71; and added new claims 72 and 73. Claims 1-15, 17-27, 72 and 73 are pending, with claims 7, 10, 13, 22-24, 26 and 27 withdrawn due to restriction.

### **Vacated Rejection**

Item 8 of the Final Office Action rejected claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, and 17-27 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111041 A1). However, item 1 of the Final Office Action also vacated item 14 of the previous Office Action dated June 27, 2007, which rejected claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, and 17-27 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111041 A1).

Applicant assumes that the rejection based on Ni et al. (US 2004/0111041 A1) was inadvertently included in the Final Office Action, in the same manner that it was inadvertently included in the previous Office Action. Applicant therefore requests that the Examiner vacate item 9 of the Final Office Action, as the Examiner did for item 14 of the previous Office Action. As was the case for Applicant's response to the previous Office Action, Applicant responds to the Final Office Action as if the rejection based on Ni et al. (US 2004/0111041 A1) was not included therein. Applicant reserves the right to supplement this Amendment if the Examiner intended to reject the claims based on Ni et al. (US 2004/0111041 A1).

### **Elections/Restrictions**

The Final Office Action noted that claims 7, 10, 13, 22-24, 26, 27 and 69-71 presented in Applicant's previous response were drawn to nonelected inventions, and suggested that a complete reply to the Final Office Action must include cancellation of the nonelected claims or other appropriate action. Applicant has canceled claims 69-71. However, claims 7, 10, 13, 22-24, 26 and 27 depend, either directly or indirectly, from claim 1, which is drawn to an elected invention. Accordingly, claims 7, 10, 13, 22-24, 26 and 27 are eligible for rejoinder in the event that independent claim 1 is allowed.

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**Claim Rejection Under 35 U.S.C. § 102**

The Final Office Action rejected claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-21 and 25 under 35 U.S.C. § 102(e) as being anticipated by Ni et al. (US 2004/0111040, herein referred to as Ni). Applicant respectfully traverses the rejection to the extent such rejection may be considered applicable to the amended claims. Ni fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(e), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Ni fails to disclose or suggest a method comprising both determining when a patient is attempting to sleep, and determining when the patient is asleep based on at least one of a plurality of monitored physiological parameters, as recited by Applicant's amended independent claim 1. In response to Applicant's arguments that Ni only teaches determining whether a patient is asleep, and does not teach or suggest determining when a patient is attempting to sleep, the Examiner pointed to the teachings in Ni regarding monitoring posture and time of day.<sup>1</sup> The Examiner argued that, because Ni teaches monitoring posture and time of day, Ni teaches determining when the patient is attempting to sleep. Applicant respectfully disagrees with this argument.

The system described in Ni compares a sleep-related signal to a threshold value and detects sleep onset and termination based on the comparison. The sleep threshold may be, for example, based on the patient's motion sensed by an accelerometer.<sup>2</sup> Ni additionally describes the use of two sleep-related conditions, such as minute ventilation and accelerometer signals, to enhance accuracy of sleep detection.<sup>3</sup> To add further robustness, a posture sensor or time may be used to confirm the detection of whether the patient is asleep.<sup>4</sup>

Ni only teaches using posture or time of day to confirm whether other sensors correctly detected that the patient is asleep. Ni does not disclose using posture or time of day to determine when the patient is attempting to sleep. Ni does not disclose or suggest determining when the patient is attempting to sleep using any sensor or technique. Ni only teaches a single determination, i.e., whether the patient is asleep, which may be confirmed by posture or time of

<sup>1</sup> Office Action dated 5/6/08, page 8, item 28.

<sup>2</sup> Ni, paragraph [090].

<sup>3</sup> Ni, paragraphs [0097] and [0098].

<sup>4</sup> Ni, paragraph [0106].

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day. In the absence of any teaching in Ni of determining when the patient is attempting to sleep, the rejection of Applicant's claims as anticipated by Ni is improper.

Ni also fails to disclose or suggest determining a value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep, wherein the activity levels are determined based on at least one physiological parameter that is indicative of patient physical activity that is monitored via at least one accelerometer, as required by amended independent claim 1. In the Final Office Action, the Examiner argued that paragraphs 132-134 of Ni disclose determining a value of at least one activity metric based on activity levels determined when the patient is not attempting to sleep. However, paragraphs 132-134 discuss detecting disordered breathing episodes when a patient is awake. Monitoring disordered breathing episodes in the manner taught by Ni is not the same as or suggestive of determining an activity metric value based on activity levels determined via at least one accelerometer, as required by amended claim 1.

With respect to claim 6, Ni fails to disclose or suggest determining when the patient is attempting to sleep based on an activity level by comparing the activity level to an activity level threshold and comparing an amount of time that the activity level remains substantially below the activity level threshold to a time threshold. The Office Action cited paragraph [0094] of Ni as describing establishing the amount of time above or below an activity threshold.<sup>5</sup> However, this portion of Ni refers to characteristics of the disordered breathing episodes. Ni does not disclose or suggest detecting sleep based on the disordered breathing episodes. Rather, Ni describes sensing signals associated with disordered breathing while the patient is asleep to detect disordered breathing episodes.<sup>6</sup> Ni does not disclose or suggest determining when the patient is attempting to sleep based on the durations of disordered breathing episodes.

Similarly, with respect to claim 11, Ni fails to disclose or suggest that the sleep quality metric comprises sleep latency and determining values of the sleep quality metric comprises identifying a first time when the patient is attempting to fall asleep, identifying a second time when the patient falls asleep based on at least one of the physiological parameters, and determining an amount of time between the first and second times. The Office Action cited

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<sup>5</sup> Office Action dated 5/6/08, pages 8-9, item 29.

<sup>6</sup> Ni, paragraph [0088].

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paragraph [0094] of Ni as teaching this requirement. However, as previously described, this portion of Ni refers to characteristics of disordered breathing episodes. The time between disordered breathing episodes is not related to sleep latency. Ni fails to disclose or suggest determining an amount of time between a first time when the patient is attempting to fall asleep and a second time when the patient falls asleep.

Ni fails to disclose each and every limitation set forth in independent claim 1. Each of claims 2, 3, 5, 6, 8, 9, 11, 12, 14, 15, 17-21, and 25 are dependent upon claim 1. For at least the reasons described with respect to independent claim 1, each of dependent claims 2, 3, 5, 6, 8, 9, 11, 12, 14, 15, 17-21, and 25 are also in condition for allowance. For at least these reasons, the Office Action has failed to establish a prima facie case for anticipation of Applicant's claims 1-3, 5, 6, 8, 9, 11, 12, 14, 15, 17-21, and 25 under 35 U.S.C. § 102(e). Withdrawal of this rejection is requested.

#### **Claim Rejection Under 35 U.S.C. § 103**

The Final Office Action rejected claim 4 under 35 U.S.C. § 103(a) as being unpatentable over Ni et al. in view of Sheldon (US 5,593,431). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Claim 4 is dependent upon claim 3, which directly depends from independent claim 1. Ni fails to disclose or suggest the requirements of claim 1 for at least the reasons stated previously in this Amendment. Sheldon lacks any teaching sufficient to overcome the basic deficiencies described above with respect to Ni. Therefore, claim 4 is also in condition for allowance. Withdrawal of this rejection is requested.

#### **New Claims**

Applicant has added claims 72 and 73 to the application. Claims 72 and 73 find support throughout the application as originally filed, including, for example, paragraph [0043] and FIG. 9. No new matter is added by the new claims.

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The applied references fail to disclose or suggest the requirements of claims 72 and 73. For example, the applied references fail to disclose or suggest indicating efficacy of a pain therapy based on the values of the at least one sleep quality metric and the value of the at least one activity metric, as required by claim 72. As another example, the applied references fail to disclose or suggest indicating efficacy of spinal cord stimulation based on the values of the at least one sleep quality metric and the value of the at least one activity metric, as required by claim 73.

### CONCLUSION

All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims.

In view of the clear distinctions identified above between the current claims and the applied prior art, Applicant reserves further comment at this time regarding any other features of the independent or dependent claims. However, Applicant does not admit or acquiesce in any of the rejections or the Examiner's interpretations of the applied references. Applicant reserves the right to present additional arguments with respect to any of the independent or dependent claims.

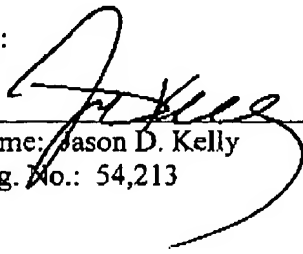
Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

7-2-08

SHUMAKER & SIEFFERT, P.A.  
1625 Radio Drive, Suite 300  
Woodbury, Minnesota 55125  
Telephone: 651.286.8350  
Facsimile: 651.735.1102

By:

  
Name: Jason D. Kelly  
Reg. No.: 54,213